Hot Issue / Briefing Paper
For Cristina Fernandez

B. Braun Medical, Inc.
Inspection Summary

Date: 11/13/18 **Lead Staff Contact/Phone #:** Gwendolyn Supplee, X-2763

Issue/Topic:

Inspection conducted on October 23, 2018, at B. Braun Medical located in Allentown, PA

Background:

- B. Braun Medical, Inc. manufactures specialty medical products in a 400,000 square foot manufacturing facility.
- The finished products require sterilization prior to use in the hospital environment.
- The sterilization is performed using ~~using~~ Ethylene Oxide (EtO), which is a Hazardous Air Pollutant (HAP) that has the potential to cause cancer.
- EPA updated its EtO cancer risk factor in 2016 and the National Air Toxics Assessment (NATA) used the revised revised risk factor in the 2018 assessment.
- There are four facilities in Region 3 which exceed the risk of 100 in 1 million; B. Braun is one of ~~the four facilities in Region 3~~them. The NATA risk factor was calculated using 2014 emissions data from facilities.
- B. Braun is regulated under MACT Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities.
- The facility has seven large sterilization units, and one smaller unit used for Research and Development and testing. There is one aeration room where all sterilized units are placed to remove any residual EtO after the sterilization process.
- The eight sterilization units are controlled by a common scrubber, and the aeration room is controlled by a catalytic oxidizer.
- OAECA conducted a full compliance evaluation of the facility and focused on the EtO emissions estimates calculated by the facility, compliance with MACT Subpart O requirements, as well as compliance with the Facility Title V Operating Permit requirements.

Direction/Decision:

- B. Braun discovered an error in the spreadsheets that it uses to calculate EtO emissions and determined that it was over-reporting EtO emissions by 0.25 tons/year for the last several years.
- B. Braun uses conservative assumptions in calculating its EtO emissions and is likely over-reporting the EtO emissions from the facility even after the correction of the error above.

- The NATA risk factor uses 2014 emissions data from the facility. Beginning in 2016, B. Braun began outsourcing some of the sterilization of its products that are manufactured in the Dominican Republic to a facility in Georgia. Prior to 2016, B. Braun sterilized these products at the Allentown facility, which resulted in higher EtO emissions. EtO emissions at the facility have been decreasing since 2016.
- The only area of concern identified during the inspection is that B. Braun does not have a copy of the initial stack test that was conducted on the scrubber to demonstrate compliance with MACT Supbart O requirements. B. Braun is using an assumed control efficiency of 99% that was not able to be corroborated by stack test data.
- The control device efficiency of 99% seems reasonable for this type of control device; EPA is going to look in the facility files and contact PADEP to see if a copy of the MACT compliance test report is located in any of these files.

Political Interest (local/state/federal/tribal):

Given the NATA data release to the public, the increased cancer risk of EtO, and the identification of B. Braun as a significant source of EtO emissions, there may be increased public interest surrounding this facility. PADEP accompanied EPA for part of the inspection.

Follow-up:

- Based on the facility inspection and the review of records, the inspection team believes did not identify any Areas of Concern that require further investigation, and no follow up actions such as a 114 Information Request is recommended at this time.